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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327

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MCLEOD MOYNE & REILLY, P.C.
2190 COMMONS PARKWAY
OKEMOS, MI 48864

EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/29/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,143

Applicant(s)

Nair et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 13, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 15-18, 27-30, and 34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 15-18, 27-30, and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1, 3-6, 15-18, 27-30 and 34 are pending in the application and were presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 3-6, 15-18, 27-30 and 34 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments were fully considered, but not found convincing.

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Applicants cite *In re Smith*, wherein appellants taught in the specification that they had “produced crystalline polymers of 4-methyl-1-pentene which have melting points in the range of 390 to 425°F” however particularly claimed 4-methyl-1-pentene which was deemed New Matter by the Examiner (p.4-Arguments). The CCPA ruled that “polymers of 4-methyl-1-pentene” was the “necessary and only reasonable construction”.

While it is true that in some circumstances, embodiments which appear to be New Matter can in fact be intrinsic to an application as demonstrated above; in the Instant case, it is not found where the Disclosure as originally filed explicitly or implicitly taught a combination of cyanidin along with a *specific* anthocyanin to inhibit prostaglandin H synthase or cyclooxygenase. Example 4 provides for assays which show where a mixture of anthocyanins and cyanidin *respectively* inhibited PGHS-1; however, there is no teaching of a mixture of *one particular* anthocyanin and cyanidin to inhibit PGHS-1. Thus, the invention *as claimed* was not the ‘necessary and only reasonable construction’ as indicated in *In re Smith*. On the contrary, it does not appear that this particular invention was disclosed within the original specification, and is actually broader in scope as it may be drawn to anthocyanins which are not particularly extracted from cherries. It is further noted that Applicants have not directed

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the Examiner toward any particular point in the application which would teach such a particular embodiment.

Thus, the rejection stands.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, and 27-30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lietti et al. (GB 1,598,294) in view of Wurm et al. (1982) for the reasons set forth in the previous Office Action.

Applicants' arguments were fully considered, but not found persuasive.

Applicants argue that Wurm et al. "Is dealing with different flavonoids which are not anthocyanins. The reference does not even disclose cyanidin" (p.1, Arguments). As indicated in the previous Office Action (Paper No. 15, it was agreed that the structure disclosed by Wurm et al. did not describe cyanidin. However, again, it was reiterated that Wurm et al. taught that "all flavonoids, regardless of the stereochemistry and degree of oxidation of their heterocyclic rings, are prostaglandin synthase (PGS) inhibitors if at least one ring has a pyrocatechol structure" (6A, 6B). Anthocyanins

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and cyanidin have a pyrocatechol structure (See Instant Fig. 1). Thus, although Wurm et al. did not specifically disclose anthocyanins per se, one of ordinary skill in the art would have had a reasonable expectation that anthocyanins, and cyanidin, would have inhibited prostaglandin synthase activity.

Wurm et al. did not disclose cyanidin; however, Lietti et al. clearly disclosed cyanidin. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that anthocyanins are not all converted to the non-glycosylated form before entry into the intestinal tract (p.2-Arguments). Applicants provide a reference by Milbury et al. which show that some anthocyanins in the glycosylated form find their way into the blood stream. However, it is noted that the reference was published after the filing date of the Instant application. The Instant specification teaches that anthocyanins were hydrolyzed in-vivo to the cyanidin and glucoside form (p.15, Instant specification). Thus, this is what was known in the art *at the time the invention was made* and was considered to be conventional knowledge, especially in view of Lietti et al. and Applicant's own specification.

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Therefore, at the time the invention was made, the ordinary artisan would have been motivated to have combined cyanidin which was known to inhibit inflammation, and flavonoids which were known to inhibit prostaglandin synthase (and consequently inflammation) to provide for an additive effect in treating inflammation. Again, at the time the invention was made, one of ordinary skill in the art would have recognized that cyanidin and anthocyanins would have been virtual pharmaceutical equivalents since anthocyanins essentially degraded in the body to cyanidin.

Claims 1, 3-6, 15-18, 27-30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lietti et al. (GB 1,598,294) in view of Wurm et al. (1982) and further in view of Heckert et al. (US 5,516,535).

Applicants' arguments were considered, however not found convincing.

Applicants argue that "the purpose of the fruit juice in the beverage is to provide flavor, not to inhibit the enzymes or inflammation as in the claimed method" (p.3-Arguments).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as pointed out in the previous Office Action, it was known in the art to combine extracts from endogenous fruit back into the pulp as a carrier for the extracts. The addition of the endogenous extract such as Vitamin C (from orange) into orange pulp would have been more attractive to the consumer in that the composition would have been enriched with Vitamin C, thereby offering a natural product with an increased amount of beneficial ingredient. Again, this reference was cited to relay the conventionality of the addition of endogenous components of fruit such as vitamins back into an edible portion of the same fruit to act as a carrier for the active ingredients.

A rejection under 35 U.S.C. § 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417.

No Claims are allowed.

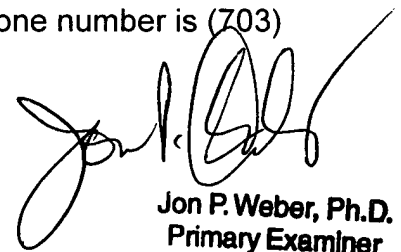
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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner